

106TH CONGRESS  
2D SESSION

# H. R. 4525

To amend the Public Health Service Act to establish a program under which the Secretary of Health and Human Services makes cash awards to private entities that discover drugs that cure or prevent diseases whose cure or prevention is designated by the Secretary as a national priority.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2000

Mr. STARK introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend the Public Health Service Act to establish a program under which the Secretary of Health and Human Services makes cash awards to private entities that discover drugs that cure or prevent diseases whose cure or prevention is designated by the Secretary as a national priority.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Affordable Break-  
5       through Drug Incentive Act of 2000”.

1 **SEC. 2. ESTABLISHMENT OF PROGRAM OF CASH AWARDS**  
2 **FOR DISCOVERY OF DRUGS PROVIDING DIS-**  
3 **EASE CURES OR PREVENTION.**

4 Part G of title IV of the Public Health Service Act  
5 (42 U.S.C. 288 et seq.) is amended by adding at the end  
6 the following section:

7 “AWARD FOR DISCOVERY OF DRUG PROVIDING DISEASE  
8 CURE OR PREVENTION

9 “SEC. 489A. (a) IN GENERAL.—From amounts ap-  
10 propriated under subsection (f), the Secretary may make  
11 a cash award to any private entity (whether nonprofit or  
12 for profit) that, under section 505(b) of the Federal Food,  
13 Drug, and Cosmetic Act, submits to the Secretary an ap-  
14 plication for a drug that is approved by the Secretary as  
15 a cure for a disease on the list under subsection (b) or  
16 as a means of preventing the occurrence of a disease on  
17 the list.

18 “(b) NATIONAL PRIORITIES FOR CURE OR PREVEN-  
19 TION; LIST OF DISEASES.—

20 “(1) IN GENERAL.—Not later than 90 days  
21 after the date on which amounts are first made  
22 available under subsection (f), the Secretary shall  
23 publish in the Federal Register a list of the diseases  
24 selected by the Secretary under paragraph (2), to-  
25 gether with a statement explaining the availability of  
26 cash awards under subsection (a) and identifying the

1 factors used by the Secretary in selecting diseases  
2 for inclusion on the list. The Secretary shall periodi-  
3 cally review the list and make any revisions deter-  
4 mined by the Secretary to be appropriate.

5 “(2) SELECTION OF DISEASES.—For purposes  
6 of awards under subsection (a), the Secretary  
7 shall—

8 “(A) identify serious diseases for which  
9 there are no cures and serious diseases for  
10 which there are no means of prevention; and

11 “(B) from among such diseases, select dis-  
12 eases whose cure or prevention should be na-  
13 tional priorities in the opinion of the Secretary,  
14 taking into account factors regarding mortality,  
15 morbidity, and economic effects, and such other  
16 factors as the Secretary determines to be appro-  
17 priate.

18 “(c) AMOUNT OF AWARD.—

19 “(1) IN GENERAL.—An award under subsection  
20 (a) may not be made in an amount exceeding  
21 \$10,000,000,000, subject to paragraph (2).

22 “(2) OFFSET OF TAX LIABILITY.—After deter-  
23 mining the amount of an award under subsection (a)  
24 (referred to in this paragraph as the ‘selected  
25 amount’), the Secretary shall increase the selected

1 amount for the purpose of providing to the recipient  
2 such reimbursement for the tax liability resulting  
3 from the award and the reimbursement as will pro-  
4 vide the recipient with an after-tax award that is  
5 substantially equivalent to the selected amount.

6 “(d) CERTAIN CONDITIONS.—

7 “(1) IN GENERAL.—An award may be made  
8 under subsection (a) only if the private entity in-  
9 volved has entered into an agreement described in  
10 paragraph (2) or an agreement described in para-  
11 graph (3). The Secretary shall determine which of  
12 such paragraphs will be applied to the entity.

13 “(2) REASONABLE PROFIT.—For purposes of  
14 paragraph (1), an agreement described in this para-  
15 graph is an agreement between the private entity in-  
16 volved and the Secretary governing the price at  
17 which the drug involved will be sold by the entity  
18 (and any successors of the entity regarding the right  
19 to market the drug commercially). In negotiating the  
20 price, the Secretary shall take into account a reason-  
21 able profit for the entity, (after allowing for a rea-  
22 sonable cost of production and overhead and admin-  
23 istrative costs), and shall consider the likely price at  
24 which the drug will be sold at retail.

25 “(3) TRANSFER OF PATENT RIGHTS.—

1           “(A) TRANSFER TO FEDERAL GOVERN-  
2           MENT.—For purposes of paragraph (1), an  
3           agreement described in this paragraph is an  
4           agreement between the private entity involved  
5           and the Secretary under which the entity trans-  
6           fers to the Secretary all rights of the entity  
7           with respect to patents for the drug involved.  
8           The agreement may provide that the Secretary  
9           will not with respect to the drug approve any  
10          application under section 505(j) of the Federal  
11          Food, Drug, and Cosmetic Act during the  
12          \*[180]-day period beginning on the date on  
13          which the rights are transferred to the Sec-  
14          retary, or during such shorter period as the  
15          Secretary and the entity designate in the agree-  
16          ment.

17          “(B) FEDERAL EXERCISE OF RIGHTS; FA-  
18          CILITATION OF GENERIC DRUG APPLICA-  
19          TIONS.—The Secretary shall assert patent  
20          rights transferred under subparagraph (A)  
21          against any private entity that seeks to claim  
22          the drug by patent. The Secretary may not as-  
23          sert such rights against any entity that with re-  
24          spect to the drug submits to the Secretary an  
25          application under section 505(j) of the Federal

1 Food, Drug, and Cosmetic Act, except that the  
2 Secretary may impose a reasonable fee for for-  
3 bearance regarding such rights. Such fees are  
4 available to the Secretary for awards under sub-  
5 section (a).

6 “(4) ADVANCE NOTICE TO AWARD CAN-  
7 DIDATE.—Upon the request of a private entity that  
8 expresses an interest in developing a drug that may  
9 be a candidate for an award under subsection (a),  
10 the Secretary may enter into an agreement with the  
11 entity specifying which of paragraphs (2) and (3)  
12 will be applied by the Secretary to the entity in the  
13 event that the entity otherwise qualifies for an  
14 award for the drug.

15 “(e) DISCRETION OF SECRETARY.—Determinations  
16 of the Secretary regarding the selection of recipients for  
17 awards under subsection (a), the amount of such awards,  
18 and the inclusion of diseases on the list under subsection  
19 (b) are committed to the discretion of the Secretary, and  
20 are not subject to judicial review.

21 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
22 purpose of carrying out this section, there are authorized  
23 to be appropriated such sums as may be necessary for  
24 each of the fiscal years 2001 through 2010.”.

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